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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,465	04/01/2004	Sonia Moreno-Lopez	MORENO-LOPEZ	8524

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,465	MORENO-LOPEZ ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/17/07 has been entered. Applicant's amendment and response also received on 8/17/07 have been entered. Claims 1-40 have been canceled and new claim 41 has been added. Claim 41 is therefore currently pending in the instant application.

The previous office action clearly indicated that previously pending claims 21-28 and 32-40 were withdrawn from consideration as being drawn to a non-elected invention. The previous office action explained in detail that the applicant had received an action on the merits for the originally presented invention, which was a vaccine product, and that this invention had been constructively elected by original presentation for prosecution on the merits. The previous office action stated that while the vaccines comprising a DNA expression construct, previously examined, and the newly presented methods of vaccinating a living being are related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the vaccines can be used to transfect cells in vitro in tissue culture and further used to produce the antigen in vitro.

As such, the search and examination for the vaccine product, and the method of vaccinating a living being is not coextensive and it would place an undue burden on the examiner to search and examine all inventions together.

In this RCE filing, the applicant has canceled all previously pending claims and submitted a single new claim, claim 41, which is drawn to the subject matter non-elected by original presentation as indicated in the previous office action and above. It appears therefore that the applicant intends to switch the elected invention from the vaccine products previously examined to the methods of eliciting an immune response previously non-elected and withdrawn from prosecution. Such a switch in the subject matter under examination during prosecution is entirely based on the discretion of the examiner of record. Upon consideration, the examiner of record agrees to examine the method of eliciting an immune responses of claim 41 in this RCE filing. However, it is noted that as the elected invention has changed, any future submission of claims drawn to the canceled subject matter of the vaccine product may result in withdrawal of those claims from prosecution.

Claim 41 is therefore under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Priority

The previous office action acknowledged applicant's claim for foreign priority based on applications filed in Germany on October 2, 2001 or November 12, 2001, but noted that while ,

the applicant has provided a certified copy of DE 101 56 678.6 in German, the office has only received a single cover page for DE 101 48 697.9, which does not constitute a certified copy. As indicated in the previous office action, a complete certified copy of DE 101 48 697.9 is required to fully comply with 35 U.S.C. 119(b).

The applicant has indicated that they will try to obtain the entire document, DE 101 48 697.9, shortly. However, as the entire document has not yet been received, the requirements for priority to DE 101 48 697.9 have not been met.

Double Patenting

The provisional rejection of claims 29-31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-23 of copending Application No. 10/816,591, hereafter referred to as the '591 application, is withdrawn over canceled claims 29-31. The provisional rejection has not been applied to new claim 41 as new claim 41 is drawn to a method of eliciting an immune response, whereas claim 24, the sole pending claim in the '591 application is drawn to a vaccine product.

Claim Rejections - 35 USC § 102

The rejection of claims 29-31 rejected under 35 U.S.C. 102(a) as being anticipated by Schirmbeck et al. (June 2001) J. Mol. Med., Vol. 79, 343-350, is withdrawn over canceled claims 29-31 and is newly applied in modified form over new claim 41. The applicant argues

that new claim 41, a method claim, is considered patentably differentiated over the prior art of record. However, this is not agreed for reasons discussed in detail below.

The claim recites a method of eliciting an immune response with a vaccine which induces protective immunity to one or more infectious diseases when administered, comprising a " type 1-cellular mediated immune-response eliciting" vaccine "being configured to be intradermally injected" into a living being where the vaccine comprises a DNA expression construct which is a covalently closed linear DNA molecule comprising a linear double stranded region comprising a coding sequence under control of a promoter, where the single strands forming the double strand are linked a short single stranded loops of DNA, and where the construct is covalently linked to an oligopeptide to increase transfection efficacy, wherein the construct encodes a hepatitis antigen. It is noted that the claim as written lacks any actual method steps. While the claim recites that the vaccine is formulated for intradermal injection, the claim does not actually recite a method step wherein the vaccine is administered to a living being, or specifically by intradermal injection. See also the rejection of the claim under 112, second paragraph, below. In addition, while the vaccine is characterized as "type 1-cllular mediated immune response eliciting", the claim does not recite in the preamble or anywhere else in the claim that the administration of the vaccine, intradermal or otherwise, results or elicits a type 1-cellular mediated immune response. In the interests of compact prosecution, the claim has been interpreted as encompassing the administration of a vaccine with the structure as claimed by any route of administration for the elicitation of any type of immune response.

Schirmbeck et al. teaches a minimal expression construct (MIDGE) comprising covalently closed linear DNA that contains only a hepatitis B surface antigen (HBsAG) coding

sequence operably linked to CMV promoter and polyA termination sequence where the linear ends are linked by short single stranded loops of DNA, and wherein the construct is further covalently linked to the nuclear localization sequence (NLS) oligopeptide PKKKRKVEDPYC (Schirmbeck et al., page 345, Figure 1 B.3). Schirmbeck et al. also teaches a vaccine comprising this construct, and methods of inducing hepatitis antigen specific immune response in vivo by intradermal or intramuscular injection of the MIDGE-peptide vaccine (Schirmbeck et al., page 346 and 348). Note as well that Schirmbeck et al. demonstrates that the MIDGE-NLS construct can induce "type 1-cellular mediated immune responses" depending on the route of administration such that the MIDGE-NLS construct encoding HBsAG meets the claim limitation that of a "type 1-cellular mediated immune-response eliciting vaccine". Thus, by teaching all the limitations of the claims as written, Schirmbeck et al. anticipates the instant invention as claimed.

The rejection of claims 29-31 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,451,593 (2002), hereafter referred to as Wittig et al., is withdrawn in view of the cancellation of claims 29-31.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 recites a method of eliciting an immune response in a living being with a vaccine which induces protective immunity to one or more infectious diseases "when administered", comprising a type 1-cellular mediated immune-response eliciting vaccine "being configured to be intradermally injected" into a living being where the vaccine comprises a DNA expression construct which is a covalently closed linear DNA molecule comprising a linear double stranded region comprising a coding sequence under control of a promoter, where the single strands forming the double strand are linked a short single stranded loops of DNA, and where the construct is covalently linked to an oligopeptide to increase transfection efficacy, wherein the construct encodes a hepatitis antigen. While the claim sets forth the structural limitations of the vaccine, the method lack any actual method step. The phrase in the preamble "when administered" is not an active step directing administration of the vaccine, neither is the identification of the vaccine as "being configured to be intradermally injected". The method as written lack a step in which the vaccine is actually administered to the living being. Since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a method without any active, positive steps delimiting how the method is actually practiced. As written, the claim represents nothing more than an intended use for the vaccine.

It is further noted that the claim as written, while identifying the vaccine as a "type 1-cellular mediated immune-response eliciting vaccine" does not appear to limit the method to the

elicitation of a type-1 cellular response, but rather appears to broadly read on the elicitation of any immune response. The method, as there are no method steps for administering the vaccine, further does not recite any result from such administration.

Thus, for the reasons outlined above, the metes and bounds of the claim cannot be determined.

As noted previously in this office action, in the interests of compact prosecution, the method has been interpreted as encompassing the administration of a vaccine with the structure as claimed by any route of administration for the elicitation of any type of immune response.

Claim 41 is not allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633